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Development of a non-invasive diagnostic technique for acetabular component loosening in total hip replacements

Abdullah A. Alshuhri*, Timothy P. Holsgrove, Anthony W. Miles, James L. Cunningham

The Centre for Orthopaedic Biomechanics, Department of Mechanical Engineering, University of Bath, Bath, BA2 7AY, United Kingdom

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ABSTRACT

Current techniques for diagnosing early loosening of a total hip replacement (THR) are ineffective, especially for the acetabular component. Accordingly, new, accurate, and quantifiable methods are required. The aim of this study was to investigate the viability of vibrational analysis for accurately detecting acetabular component loosening.

A simplified acetabular model was constructed using a Sawbones® foam block. By placing a thin silicone layer between the acetabular component and the Sawbones block, 2- and 4-mm soft tissue membranes were simulated representing different loosening scenarios. A constant amplitude sinusoidal excitation with a sweep range of 100–1500 Hz was used. Output vibration from the model was measured using an accelerometer and an ultrasound probe. Loosening was determined from output signal features such as the number and relative strength of observed harmonic frequencies.

Both measurement methods were sufficient to measure the output vibration. Vibrational analysis reliably detected loosening corresponding to both 2 and 4 mm tissue membranes at driving frequencies between 100 and 1000 Hz ($p < 0.01$) using the accelerometer. In contrast, ultrasound detected 2-mm loosening at a frequency range of 850–1050 Hz ($p < 0.01$) and 4-mm loosening at 500–950 Hz ($p < 0.01$).

1. Introduction

One million total hip replacement (THR) operations are conducted annually worldwide, and this number is predicted to increase [1]. Within the first ten years of THR, around 10% of all implants are expected to fail, with loosening being the most common reason [2]. The diagnostic approaches to detect loosening are generally categorised into two groups: imaging and non-imaging approaches [3].

Radiology is the most commonly used diagnostic method and consists of different sub-techniques that can be used depending upon need. These techniques generally inspect the bone and implant interfaces to identify osseointegration, failure, or fractures [4]. However, due to the diffraction effects associated with x-ray scattering, it may be difficult to diagnose early loosening using radiological imaging techniques, especially for the acetabular component [5,6]. Even though imaging has a sensitivity and specificity of up to 80% for loosening detection, revision operations on a well-fixed implant may still occur [7].

Vibration analysis is a mechanical non-destructive technique that is widely used to inspect composite materials and structural integrity, and it has been successfully expanded into the arena of biomechanics [5]. This technique predominantly measures the response to low-frequency excitation that is reflected from the targeted surface or structure [8]. In the early 1930s, Lippmann [9] pioneered vibration analysis in medical research, utilising the stethoscope to examine bone fractures and using his fingers to elicit the input vibration. As technology developed, research groups had better tools at their disposal to investigate and develop a clinical diagnostic instrument; this was realised in the works of Chung et al. [10] and Poss et al. [11], who used vibration analysis to study the process of prosthetic fixation using bone cement. They implied that by using vibration analysis and monitoring the resonance frequency shift phenomena, it is possible to estimate implant fixation states. In this scenario, the implant osseointegration process is reflected by a gradual increase in the frequency response. Further studies also were conducted [12–19] to measure the dynamic properties of the implant in order to identify different interference changes.

Rosenstein et al. [20] were one of the first groups to utilise vibration analysis both *in vivo* and *in vitro* in a clinical study. They showed that a secure prosthesis would respond with a single frequency

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[*] Corresponding author. University of Bath, The Centre for Orthopaedic Biomechanics, Department of Mechanical Engineering, Claverton Down, Bath, BA2 7AY, UK, Tel.: +44 01225384187, fax: +44 01225386928.

E-mail addresses: A.Alshuhri@bath.ac.uk, aashuhri@hotmail.com (A.A. Alshuhri), T.P.Holsgrove@bath.ac.uk (T.P. Holsgrove), A.W.Miles@bath.ac.uk (A.W. Miles), J.L.Cunningham@bath.ac.uk (J.L. Cunningham).

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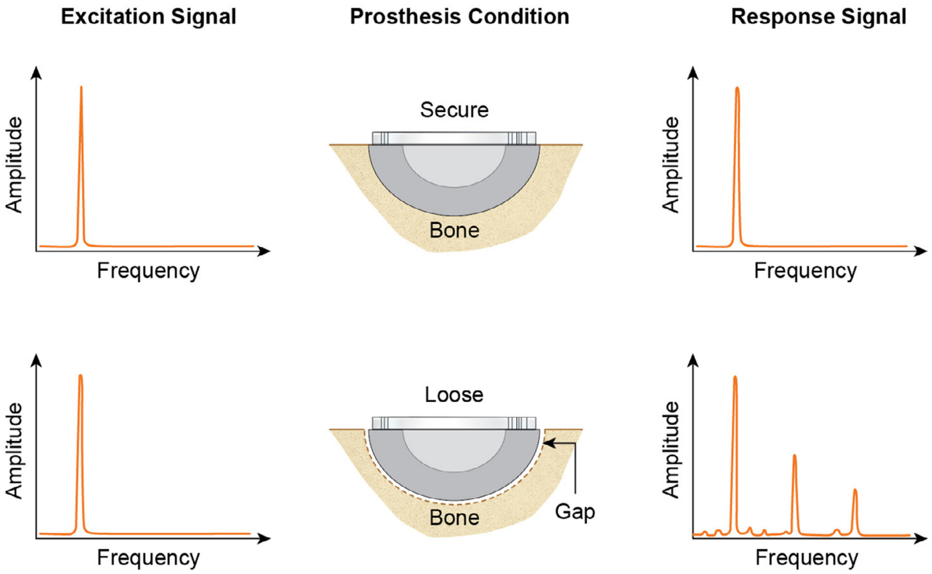

Fig. 1. Vibration analysis concept showing the difference between the secure and loose acetabular cup prostheses.

vibration, whereas a loose prosthesis would vibrate at different frequencies appearing as different peaks in the frequency spectrum; this vibration analysis concept is simplified for the acetabular component, as presented in Fig. 1.

Li et al. [21,22] were the next to explore vibration analysis, showing that the early prosthetic loosening diagnosis has a poor sensitivity (37.5%), but that it could reliably detect late loosening. Georgiou and Cunningham [23] also compared vibration analysis with standard radiological assessment and demonstrated that vibration analysis improved diagnostic precision by 20%; moreover, they were able to detect 13% more cases than radiological diagnosis with 81% sensitivity and 89% specificity. Other research groups have used vibration analysis for different orthopaedic applications such as; the telemetry technique to assess THR femoral loosening [24–26], trans-femoral osseointegration [27–29], intra-operative initial implant stability [6,30–33], THR femoral stability utilising acoustic resonance responses [7,34–41], and complete THR component loosening (femoral and acetabular) [5].

Rowlands et al. [42] investigated replacement of the accelerometer sensor with an ultrasound probe to overcome the effect of soft tissue damping. Their approach used excitation frequencies <1500 Hz on two different types of bone analogues, Sawbones® and Tufnol®. Initially, the Sawbones femur was tested with both a fixed and loose hip prosthesis by using cement fixation. The Tufnol femur was then tested for three interface conditions by using different diameter solid bars of varied fits (fixed, sliding, and loose). Ultrasound distinguished between the secure and loose states with a noticeably higher signal magnitude than the accelerometer.

The majority of previous studies on vibration analysis [20–24,35–42] assessed loosening of the femoral stem. Since a high rate of loosening in the acetabular component has been reported in the clinically [43]; therefore, the aim of the present study was to compare ultrasound and accelerometer methods and to examine the viability of the vibration analysis technique to accurately detect acetabular component loosening.

2. Materials and methods

A simplified model was constructed to mimic different scenarios of acetabular cup loosening. A secure component was represented by a tight press-fit of the acetabular cup in polyurethane solid foam (Sawbones) blocks with a hemispherical cavity. By placing a thin layer of low modulus silicone (EVO-STIK, Bostik Limited, England) between the acetabular component and the Sawbones block, the loosening effects of 2 and 4 mm soft tissue interfaces were simulated. To represent healthy bone density, blocks with a density of 0.48 g/cm^3 (Sawbones Europe AB, Malmö, Sweden) were used, with two acetabular cups having outside diameters of 54 and 52 mm, respectively (Trident® Hemispherical cup, Stryker Orthopaedics, Mahwah, New Jersey, USA), as shown in Fig. 2.

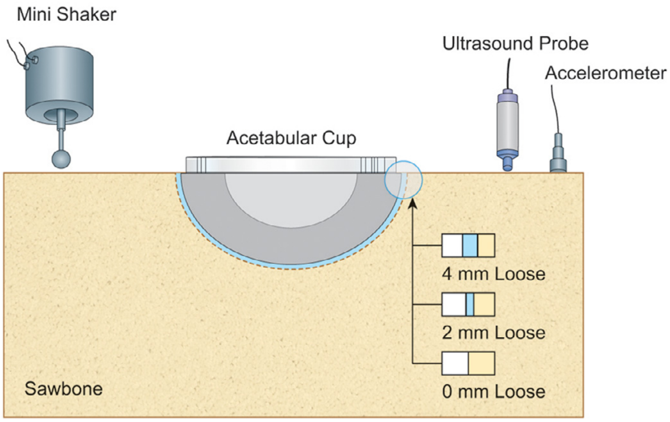

Fig. 2. The Sawbones block showing the excitation and measurement methods.

The secure Sawbones block cavity (diameter 53 mm) was machined using a computer numerically controlled (CNC) milling machine. Subsequent cavities to simulate loosening were created using acetabular reamers to give cup cavity diameters of 56 and 60 mm. This created a gap between the cup shell and the block cavity surface, as shown in Fig. 3. The secure acetabular cup scenario (0-mm loosening) involved using the 54-mm acetabular cup press-fitted in a 53-mm diameter Sawbones block cavity until it was immovable. The 2- and 4-mm loose cup scenarios were produced using the 52-mm acetabular cup placed into Sawbones blocks with cup cavity diameters of 56 and 60 mm, respectively, as shown in Fig. 3. In both loosening scenarios, a silicone layer between the acetabular cup and the Sawbones interface was used to mimic the soft tissue interface in accordance with previous studies [21,22]. Each scenario was exposed to a vibration sweep range of 100–1500 Hz using a mini shaker (V201, LDS Ltd, UK). The Sawbones block setup was lightly suspended to create a repeatable boundary condition, (Fig. 4a).